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**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE SELENIOUS ACID LITIGATION

C.A. No. 2:24-cv-07791 (BRM) (CLW)
(Consolidated)

**PLAINTIFF’S ANSWER TO DEFENDANT GLAND PHARMA LIMITED’S ANSWER
TO COMPLAINT FOR PATENT INFRINGEMENT,
AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Plaintiff/Counterclaim Defendant American Regent, Inc. (“ARI”), by its undersigned attorneys, hereby responds to the Answer, Affirmative Defenses, and Counterclaims of Defendant/Counterclaimant Gland Pharma Limited (“Gland”) (ECF No. 61; hereinafter, the “Counterclaims”) as follows:

GENERAL DENIAL

ARI denies all allegations in Gland's Counterclaims except for those specifically admitted below. With respect to the allegations made in the Counterclaims, upon knowledge with respect to ARI's own acts, and upon information and belief as to other matters, ARI responds and alleges as follows:

GLAND'S COUNTERCLAIMS

1. Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Gland Pharma Limited ("Gland"), by and through its counsel, for its Counterclaim against Plaintiff, American Regent, Inc. (herein "ARI" or "Counterclaim-Defendant"), hereby states the following:

ANSWER: Paragraph 1 states legal conclusions for which no response is required. To the extent a response is required, ARI admits that Gland purports to bring the Counterclaims pursuant to Rule 13 of the Federal Rules of Civil Procedure. ARI denies the remaining allegations in Paragraph 1.

2. This is an action for a declaratory judgment of non-infringement and invalidity of the claims of U.S. Patent No. 12,150,957 (the "'957 patent" or "Counterclaim Patent-In-Suit") pursuant to the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, and provisions of the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(C).

ANSWER: Paragraph 2 states legal conclusions for which no response is required. To the extent a response is required, ARI admits that Gland purports to bring the Counterclaims under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, and provisions of the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(C). ARI does not contest subject matter jurisdiction in this judicial district for the purposes of this action only. ARI denies that the Counterclaims have merit or that Gland is entitled to any relief on its Counterclaims.

3. Upon information and belief, a true and complete copy of the '957 patent is attached to the Defendant, Gland Pharma Limited's Answer to Complaint, Affirmative Defenses and Counterclaim as Exhibit A.

ANSWER: ARI admits that Gland purports to attach a true and complete copy of the

'957 patent to Gland's Answer and Counterclaims.

THE PARTIES

4. Counterclaim-Plaintiff Gland Pharma Limited is a corporation organized and existing under the laws of India with a place of business at Survey No. 143-148, 150 & 151 Near Gandimaisamma 'X' Roads D.P. Pally, Dundigal Gandimaisamma Mandal MedchalMalkjgiri District, Hyderabad 500043, Telangana, India.

ANSWER: On the basis of Gland's Answer to Paragraph 3 in the Counterclaims, admitted.

5. Upon information and belief, and based upon the Complaint filed in the above-referenced case, Counterclaim-Defendant, American Regent, Inc., is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967.

ANSWER: Admitted.

JURISDICTION

6. This Court has subject matter jurisdiction over this Counterclaim for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202, based on an actual controversy between Counterclaim-Plaintiff, on the one hand, and the Counterclaim-Defendant on the other hand, arising under the Patent Laws of the United States, 35 U.S.C. § 1 et seq.

ANSWER: Paragraph 6 states legal conclusions for which no response is required. To the extent a response is required, ARI admits that Gland purports to bring the Counterclaims under the patent laws of the United States and 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202. ARI does not contest subject matter jurisdiction in this judicial district for the purposes of this action only. ARI denies that the Counterclaims have merit or that Gland is entitled to any relief on its Counterclaims.

7. This Court has personal jurisdiction over Counterclaim-Defendant based, inter alia, on the filing by Counterclaim-Defendant of this lawsuit in this Court.

ANSWER: Paragraph 7 states legal conclusions for which no response is required. To the extent a response is required, ARI does not contest personal jurisdiction for purposes of this action only. ARI otherwise denies the allegations of Paragraph 7.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b)(1) and 1400(b).

ANSWER: Paragraph 8 states legal conclusions for which no response is required. To the extent a response is required, ARI does not contest venue in this judicial district for the purposes of this action only. ARI otherwise denies the allegations of Paragraph 8.

ORANGE BOOK LISTING OF THE COUNTERCLAIM PATENT-IN-SUIT

9. The Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act require New Drug Application (“NDA”) holders to disclose to the FDA the patent numbers and expiration dates of those patents that the holder believes claim the "drug" for which their NDA is submitted, or patents covering a "method of using such drug." 21 U.S.C. §§ 355(b)(1)(viii) and (c)(2).

ANSWER: Paragraph 9 states legal conclusions for which no response is required. To the extent a response is required, admitted.

10. On information and belief, Counterclaim-Defendant holds NDA No. 209379 for selenious acid (“ARI NDA” and “ARI NDA Product,” respectively).

ANSWER: Admitted.

11. On information and belief, Counterclaim-Defendant owns and holds the exclusive right to enforce the '957 patent.

ANSWER: Admitted.

12. On information and belief, on November 26, 2024, the U.S. Patent and Trademark Office ("PTO") issued the '957 patent.

ANSWER: Admitted.

13. On information and belief, pursuant to 21 U.S.C. §§ 355(b)(1), Counterclaim-Defendant caused the FDA to list the Counterclaim Patent-In-Suit in the Orange Book in connection with the ARI NDA.

ANSWER: Admitted.

14. By maintaining the listing of the Counterclaim Patent-In-Suit in the Orange Book, Counterclaim-Defendant represents to the world its intent to enforce the Counterclaim Patent-In-Suit against any person not licensed by ARI engaged in the manufacture, use, sale, or importation of selenious acid before the expiration of the Counterclaim Patent-in-Suit.

ANSWER: Denied.

GLAND'S ABBREVIATED NEW DRUG APPLICATION

15. Gland filed ANDA No. 219629 (the "Gland ANDA") with the FDA. Gland's ANDA included a Paragraph IV Certification to the Counterclaim Patent-In-Suit, certifying that to the best of its knowledge that all of the claims of the Counterclaim Patent-In-Suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer to sell, and/or importation of the product described in the Gland ANDA.

ANSWER: ARI admits Gland notified ARI that Gland submitted ANDA No. 219629 to market a generic version of Selenious Acid Injection USP prior to the expiration of the '957 patent. ARI further admits that the Gland Notice Letter contained arguments and/or positions that the '957 patent is invalid and/or not infringed, which are not grounded in fact or law and raise material issues to be resolved in later stages in this proceeding, including claim construction issues and patent infringement and validity issues that will be the subject of fact and expert discovery, neither of which have occurred. ARI denies that Gland's factual and legal bases have merit. ARI otherwise denies the allegations in Paragraph 15.

16. On December 20, 2024, Gland properly notified ARI that Gland had submitted the Gland ANDA to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) as required in accordance with 21 U.S.C. § 355(j)(2)(B) ("Gland's December 20, 2024 Notice Letter"). Included with Gland's December 20, 2024 Notice Letter was an Offer of Confidential Access to Gland's ANDA in accordance with 21 U.S.C. § 355(j)(5)(C)(III).

ANSWER: ARI admits Gland notified ARI that Gland submitted ANDA No. 219629 to market a generic version of Selenious Acid Injection USP prior to the expiration of the '957 patent. ARI further admits that the Gland Notice Letter contained arguments and/or positions that the '957 patent is invalid and/or not infringed, which are not grounded in fact or law and raise material issues to be resolved in later stages in this proceeding, including claim construction issues and patent infringement and validity issues that will be the subject of fact and expert discovery, neither of which have occurred. ARI denies that Gland's factual and legal bases have merit. ARI otherwise denies the allegations in Paragraph 16.

THE PRESENCE OF A CASE OR CONTROVERSY

17. By maintaining the Orange Book listing of the Counterclaim Patent-In-Suit in connection with the ARI NDA, Counterclaim-Defendant indicates its intent to enforce the Counterclaim Patent-In-Suit.

ANSWER: Denied.

18. By maintaining the Orange Book listing of the Counterclaim Patent-In-Suit in connection with the ARI NDA, Counterclaim-Defendant is preserving its ability to pursue Gland, for a claim of infringement of the Counterclaim Patent-In-Suit at any time.

ANSWER: Denied.

19. Resolving Gland's Counterclaim is necessary to eliminate all foreseeable potential risk that Plaintiff will later assert the Counterclaim Patent-In-Suit to try to frustrate Gland's ability to market its ANDA product.

ANSWER: ARI lack sufficient knowledge and information to form a belief as to the truth of the allegations of Paragraph 19 as pled and denies those allegations on that basis.

20. There has been, and is now, an actual and justiciable controversy between Counterclaim-Plaintiff on the one hand, and Counterclaim-Defendant, on the other hand, as to whether the products disclosed in Gland's ANDA infringe the Counterclaim Patent-In-Suit, and whether any claim in the Counterclaim Patent-In-Suit is valid or enforceable.

ANSWER: Paragraph 20 states legal conclusions for which no response is required. To the extent a response is required, ARI admits there is a present, genuine, and justiciable controversy that exists between ARI and Gland regarding Gland's infringement of the '957 patent. ARI specifically denies that there is a present, genuine, and justiciable controversy regarding invalidity of the '957 patent.

21. In light of all the circumstances, an actual substantial and continuing justiciable controversy having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaim-Defendant and Counterclaim-Plaintiff as to whether the claims of the Counterclaim Patent-In-Suit are invalid and/or not infringed by Counterclaim-Plaintiff.

ANSWER: Paragraph 21 states legal conclusions for which no response is required. To the extent a response is required, ARI admits there is a present, genuine, and justiciable controversy

that exists between ARI and Gland regarding Gland's infringement of the '957 patent. ARI specifically denies that there is a present, genuine, and justiciable controversy regarding invalidity of the '957 patent.

22. This is an exceptional case entitling Gland to an award of its reasonable attorney's fees in connection with the underlying Action and this Counterclaim in accordance with 35 U.S.C. § 285.

ANSWER: Denied.

COUNT I

(Declaratory Judgment of Non-Infringement of the Counterclaim Patent-in-Suit)

23. Counterclaim-Plaintiff repeats and incorporates by reference Paragraphs 1-22 of the Counterclaim, above, as if fully set forth herein.

ANSWER: No response is required to the general re-allegation and incorporation by reference of the foregoing paragraphs of the Counterclaims. To the extent a response is required, ARI incorporates the answers in response to the foregoing paragraphs as if fully set forth herein.

24. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Counterclaim-Plaintiff and Counterclaim-Defendant concerning the Counterclaim Patent-In-Suit and the claims of the Counterclaim Patent-In-Suit.

ANSWER: Paragraph 24 states legal conclusions for which no response is required. To the extent a response is required, ARI admits there is a present, genuine, and justiciable controversy that exists between ARI and Gland regarding Gland's infringement of the '957 patent.

25. Gland's ANDA and the product described therein do not and would not, following FDA approval, infringe any valid claim of the '957 patent either directly or indirectly.

ANSWER: Denied.

26. Counterclaim-Plaintiff is entitled to a declaration that Gland's ANDA and the manufacture, use, offer for sale, sale, and/or importation of Gland's ANDA product does not infringe any valid claim of the '957 patent.

ANSWER: Denied.

COUNT II

(Declaratory Judgment of Invalidity/Unenforceability of the Counterclaim Patent-in-Suit)

27. Counterclaim-Plaintiff repeats and incorporates by reference Paragraphs 1-26 of the Counterclaim, above, as if fully set forth herein.

ANSWER: No response is required to the general re-allegation and incorporation by reference of the foregoing paragraphs of the Counterclaims. To the extent a response is required, ARI incorporates the answers in response to the foregoing paragraphs as if fully set forth herein.

28. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient, immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between the Counterclaim-Plaintiff and Counterclaim-Defendant concerning the claims of the Counterclaim Patent-In-Suit.

ANSWER: Paragraph 28 states legal conclusions for which no response is required. To the extent a response is required, ARI admits there is a present, genuine, and justiciable controversy that exists between ARI and Gland regarding Gland's infringement of the '957 patent. ARI specifically denies that there is a present, genuine, and justiciable controversy regarding invalidity of the '957 patent.

29. The '957 patent is invalid at least on one or more of the grounds that the '957 patent claims and the inventions described therein are anticipated by one or more prior art references as of the time of the alleged inventions, pursuant to 35 U.S.C. § 102, would have been obvious to persons of ordinary skill in the art as of the time of the invention, pursuant to 35 U.S.C. § 103, and/or fail to satisfy the definiteness, written description and/or enablement requirements set forth in 35 U.S.C. § 112.

ANSWER: Denied.

30. Counterclaim-Plaintiff is entitled to a declaration that the claims of the Counterclaim Patent-In-Suit are invalid under one or more provisions of 35 U.S.C. §§ 102, 103, or 112, or other judicially-created bases for invalidation/unenforceability.

ANSWER: Denied.

PRAYER FOR RELIEF

ARI denies that Gland is entitled to any judgment or relief against ARI and, therefore specifically denies Paragraphs (A)–(F) of Counterclaimant Gland’s Prayer for Relief.

Each averment and/or allegation contained in Gland’s Counterclaims that is not specifically admitted herein is hereby denied.

ARI requests that judgment be entered in its favor, dismissing Gland’s Counterclaims with prejudice, awarding ARI’s attorneys’ fees and costs incurred in this litigation under 35 U.S.C. § 285, and granting even further relief as the Court may deem just and proper.

Dated: January 28, 2025

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American Regent, Inc.*

CERTIFICATE OF SERVICE

I hereby certify that on January 28, 2025, a true and correct copy of Plaintiff's Answer to Defendant/Counterclaim Plaintiff Gland Pharma Limited's Answer to Complaint for Patent Infringement, Affirmative Defenses, and Counterclaims was served by ECF on all counsel of record and electronic mail on all counsel of record for Gland.

Date: January 28, 2025

s/ Charles H. Chevalier

Charles H. Chevalier